EXHIBIT

6

5. Prescription Accuracy and Appropriate Dispensing Standards

Filling prescriptions accurately and dispensing them appropriately are highly essential elements of quality pharmacy practice. The company expects that the standards for prescription accuracy and appropriate dispensing outlined herein will be met consistently.

An accurate prescription is one that is prepared and dispensed exactly as ordered by the prescriber and consists of the following:

- Correct name of patient;
- Correct name of practitioner;
- Correct strength and quantity;
- Correct medication; and
- Correct directions, as ordered.

An appropriately dispensed prescription is one which:

- The pharmacist believes in good faith was issued for a legitimate medical purpose;
- Resulted from a bona-fide prescriber-patient relationship;
- Satisfactorily passed a comprehensive drug utilization review by a pharmacist;
- Counseling was offered and, unless refused, provided effectively by a pharmacist;
- The prescription was accurately and responsibly billed; and
- Was surrendered to the correct patient or an authorized patient representative along with any required paper documents that correspond to that patient or that prescription.

Exhibit 0021

RETAIL PHARMACY POLICIES AND PROCEDURES

==========

Pharmacists have a professional duty to ensure that prescriptions are filled accurately and dispensed appropriately in compliance with all applicable laws. The company recommends operational workflow processes and provides technological tools to assist pharmacists in fulfilling this duty including, but not limited to, procedures and tools for prescriber verification, drug utilization review, roving patient, scan verify, Out-Window scanning, and biometric verification. The company expects all pharmacy associates to be knowledgeable about, and to use appropriately, the workflow processes and technological tools provided. However, following recommended procedures or reliance on technological tools or ancillary personnel does not displace a pharmacist's ultimate professional responsibility for ensuring that prescriptions are filled and dispensed accurately and in compliance with the law.

b. Diversion, Abuse, and Misuse of Medications

Federal law assigns pharmacists and prescribers corresponding responsibility to recognize and prevent diversion and abuse of controlled substances. Similarly, the law assigns pharmacists the obligation to exercise professional judgment in filling prescriptions only in situations that a bona fide prescriber-patient relationship exists and to otherwise comply with the law as it applies to each prescription. The company encourages the use of available resources and tools that aid these determinations. Further, the company supports a pharmacist's right to decline to provide any product or service in situations where available resources have been utilized and the pharmacist has formed a professional judgment in good faith that the product or service is not intended to be used for a legitimate medical purpose. All measures taken to determine the legitimacy of a prescription must be documented.

i. Prescriber DEA Numbers

A prescription for a controlled substance that does not include a valid, active DEA number is not a legally-issued prescription and should not be filled. The company provides various resources and system tools for validating DEA numbers. Failure to use the resources and tools to validate the legal authority of the prescriber and the validity of a prescription may result in corrective action.

ii. Suspected Prescription Forgeries

Suspected prescription forgeries must be handled as follows:

- The **actual prescriber must be contacted** and the authenticity of the prescription confirmed directly and personally by the prescriber.
- Prescription forgeries are a crime committed against the prescriber and should be reported to law enforcement by the prescriber upon discovery. In certain circumstances, it may be appropriate or required by law for a pharmacy associate to initiate the law enforcement report. In these circumstances, PPSD should be contacted for guidance prior to making the report. In every instance, pharmacy associates should cooperate with a law enforcement investigation of a prescription forgery.

- Associates must never attempt to detain anyone suspected of passing a fraudulent prescription. If law enforcement intends to detain or arrest an individual suspected of a prescription forgery on store premises, the DPM or another member of senior pharmacy management must be notified.
- Any effort to fraudulently obtain prescription drugs, particularly controlled substances, through use of telephone, forged, or altered prescriptions must be documented in the notes field in the pharmacy system and on the prescription hard copy.
- All information pertaining to a forgery investigation is highly confidential and must not be divulged to anyone other than appropriate authorities, the DPM, and PPSD.
- Any information provided to law enforcement as part of a forgery investigation must be copied or otherwise duplicated and also sent to PPSD within 48 hours of release.

If this protocol does not appear to fit the unique circumstances of a given situation, PPSD must be contacted for guidance before taking further action.

5. Partial Filling of Prescriptions

Prescriptions that are dispensed in a partial quantity of the amount prescribed must be handled and transacted appropriately to ensure that the pharmacy does not bill for any quantity of medication not dispensed.

a. Partial-Fill Processing

For all partial-fill dispensing, the transaction should be handled as follows:

- Ask the patient to select from one of the following options for tendering the remaining product.
  - Option 1: The remainder of the filled prescription may be mailed (or delivered, if pharmacy delivery services are available); or
  - Option 2: The remainder of the filled prescription may be picked up from the pharmacy; however, the patient must be informed that the remainder of the prescription will be mailed at no charge if not picked up.

  If product must be ordered, determine when the product will arrive and provide an adequate quantity to allow for mail time, if applicable.
- Process the prescription for the full quantity through the new prescription or refill prescription entry wizard to verify the patient and drug eligibility.
- Verify the patient's mail and email addresses, if applicable, and update as necessary.
- At the Fill Station, scan verify the prescription. Select the "Partial Fill" button, enter the partial-fill quantity dispensed, and press "OK." The vial label for the initial dispensing will print. Continue filling the prescription. The transaction for the balance will transition to the automated processing queue for later processing upon arrival of the additional product. (Note: The initial adjudication is reversed when performing a partial fill on prescription billed to a third party payer; however, the copay amount from the prior adjudicated claim is maintained on the receipt of the partial fill. This allows the pharmacy to change the copay amount to the customer on the initial portion of the partial fill. Documentation of the partial fill pricing is automatically updated in the dispense notes of the prescription. Once the remaining quantity is received in the pharmacy, the remaining quantity can be dispensed to the customer at no additional charge. *See* the following Prescription Balance Dispensing instructions.)

b. Prescription Balance Dispensing

Prepare and package the prescription balance in compliance with the patient's indicated preference, utilizing mail or delivery services (within 24 hours, as required) as the preferred method whenever possible and available. As indicated above, the completion portion of the partial fill is dispensed at no charge since the copay or full cash price was charged on the initial fill of the prescription. Notes indicating how payment was obtained are indicated in the dispense notes of the prescription.

For schedule II prescriptions, the balance of the medication must be received and filled within 72 hours or a new prescription will be required. If the completed prescription goes out of date, the prescription must be mailed or delivered following established company procedures.

In all instances, if the prescription balance is not dispensed before the prescription is out of date, the prescription must be voided, the patient must be appropriately notified, and any copayment received in excess of the cash price of the product dispensed must be credited or refunded.

From: Pharmacy Compliance
Sent: Thursday, August 08, 2013 10:09 AM
Cc: Price, Nikki; Riley, Bobbie; Dalponte, Anthony
Subject: Appropriate Dispensing of Controlled Substances
Attachments: DSN Controlled Substance CE.pdf; Appropriate Dispensing of Controlled Substances.pdf

To: All Pharmacists, Acme, Shaws, Jewel-Osco, NW, IMW, SoCal (Bcc: abs.dh.rx)
From: Pharmacy Compliance

Pharmacy Teams

The Pharmacy Practice Act indicates that pharmacists have a corresponding responsibility and to use their professional judgment in determining whether a prescription has a legitimate medical purpose and the practitioner is prescribing within their scope of practice. Attached is a document pharmacists can utilize to help identify potential red flags on prescriptions and the resources that are available as well as a continuing education on dispensing controlled substances.

If you have any questions, please contact Nikki Price or Pharmacy Compliance at 847-916-4709, option 2.

Nikki Price, RPh
Director of Pharmacy Compliance

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Appropriate Dispensing of Controlled Substances

The federal Controlled Substances Act assigns pharmacists and prescribers corresponding responsibility to appropriately dispense controlled substances. This means pharmacists must use professional judgment in determining if a prescription was prescribed for a legitimate medical purpose by a prescriber acting in the ordinary course of his/her professional practice. Below are examples of red flags that may warn a pharmacist that additional research is warranted, using the appropriate tools and resources available:

- ☑ Patients that pay cash for controlled substance prescriptions or upon rejection by a third party plan, requests to pay cash for a controlled substance prescription
- ☑ Pattern prescribing, i.e. many patients receiving same combo/cocktail of prescriptions (opioid/benzodiazepine/muscle relaxer)
- ☑ A common prescriber writing prescriptions for the same drug, same quantity and same strength for multiple patients
- ☑ Patients residing outside locale of store and prescriber
- ☑ Prescriber is not associated with a pain management practice (pediatrician, gynecologist, etc.) or the prescription is otherwise outside the scope of the prescriber's practice
- ☑ Patients requesting brand name products
- ☑ Shared addresses by patients presenting the same or similar prescriptions from the same prescriber
- ☑ When reviewing the patient profile, there is evidence that the patient has been prescribed controlled substances by multiple prescribers.
- ☑ Patients receiving large quantities of controlled substances
- ☑ Patients commonly presenting prescriptions on weekends or late in the day
- ☑ New patients who have been turned away from other pharmacies

If one or more red flags exist, the pharmacist must exercise professional judgment in deciding whether to dispense the prescription and use available resources, as necessary and appropriate, including the following:

- Refer to the state's Prescription Monitoring Program (PMP)
  - Practitioners, including pharmacists, have to register as an individual. Links to available PMPs are listed on the pharmacy portal on the front page of the myAlbertsons.com portal under "State Specific Links."
  - All pharmacists should register for access if applicable.
  - Check new or unknown patients for CIIs and CIIIs.
  - Review prescriptions for oxycodone 15 or 30mg.
  - Document the PMP check in the patient profile with the date, initials, and resultant action taken (i.e. *6/27/13, NMP, checked PMP, dispensed oxycodone*). If the resultant action is not to dispense the prescription, document the same in

the patient profile. In the situation the patient is a new patient to the pharmacy, create a patient profile so the note can be documented.
    - The PMP is only to be used as an additional resource in filling a prescription, and not to be used as an investigative tool

- Request ID from a new or unknown patient
    - If not already required by state law, document the type of identification verified in the pharmacy system as follows: "Verified ID-Driver's license." Unless required by law, do not record any identification numbers in the note or the patient profile.
- Verify the prescriber's DEA registration number, office address, and telephone number
    - Don't call the telephone number on the prescription. Instead, independently verify the phone number using the computer or local telephone directory.
- Verify the intended dosage with the prescriber
    - Document any discussions with a prescriber regarding the intended dosage on the hard copy of the prescription and rescan it into the pharmacy system.
    - When speaking with the prescriber, the conversation should remain friendly and professional.
        - For example, "Hello, this is Jane Doe, pharmacist at SavOn pharmacy. I am calling regarding a prescription for Mrs. Smith. I wanted to verify I have appropriately interpreted the doctor's instructions in regards to the dose. Could I please verify this with the prescriber?"

If, after careful review, the pharmacist decides that filling the prescription is not in the best interest of the patient, the pharmacist should convey this to the patient in a professional and patient friendly manner. The patient is still a patient of our store, and should be treated as such. For example, "I am sorry Mrs. Smith, after reviewing the prescription and speaking with your physician, I don't believe filling this prescription is in your best interest." Unless the prescription was determined to be forged or otherwise fraudulent, the prescription should be returned to the patient.

Additional information and resources on the appropriate dispensing of controlled substances may be found at:

www.deadiversion.usdoj.gov

In addition, a continuing education program has been placed on the Pharmacy Education portal page titled, *"Drug Store News: Pharmacists' responsibility in appropriately dispensing controlled substances".*

Pharmacist CE LESSON

DRUG STORE CE NEWS PHARMACIST

By Mary Jo Carden, RPh, JD, Director, Regulatory Affairs Academy of Managed Care Pharmacy

Author Disclosures: Mary Jo Carden and *DSN* editorial and continuing education staff do not have any actual or potential conflicts of interest in relation to this lesson.

This lesson is supported by an educational grant from Anda

Universal program number: 401-000-12-012-H03-P
Activity type: Knowledge-based
Initial release date: Dec. 3, 2012
Planned expiration date: Dec. 3, 2015
This program is worth two contact hours (0.2 CEUs).

Target Audience
Pharmacists in community-based practice.

Program Goal
To provide pharmacists with tools and tips on fulfilling their role in appropriate controlled substance dispensing.

Learning Objectives
Upon completion of this program, the pharmacist should be able to:
1. Explain the Drug Enforcement Administration's definition of the "corresponding responsibility" between prescribers and pharmacists to ensure that controlled substance medications are only dispensed to patients based on prescriptions written for a legitimate medical purpose and in the normal course of professional practice, including the pharmacist's responsibility in conducting due diligence.
2. Describe current initiatives by the DEA, Food and Drug Administration, Office of National Drug Control Policy and general state policies to curb misuse, abuse and diversion of controlled substances and their relationship to pharmacy practice.
3. List current initiatives by third-party payers, the Medicare Part D program and state Medicaid programs to curb misuse, abuse and diversion of controlled substances.
4. Understand practical approaches and actions that can be taken by the pharmacist and the pharmacy staff to reduce the likelihood of misuse, abuse and diversion of controlled substances.
5. Develop a checklist for the pharmacy staff to use in conducting due diligence, including identifying prescribers and patients that may be involved in potentially inappropriate prescribing.
6. Discuss available resources to develop effective, comprehensive controlled substance dispensing protocols in pharmacies.

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ACPE

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(CE enrollment #)

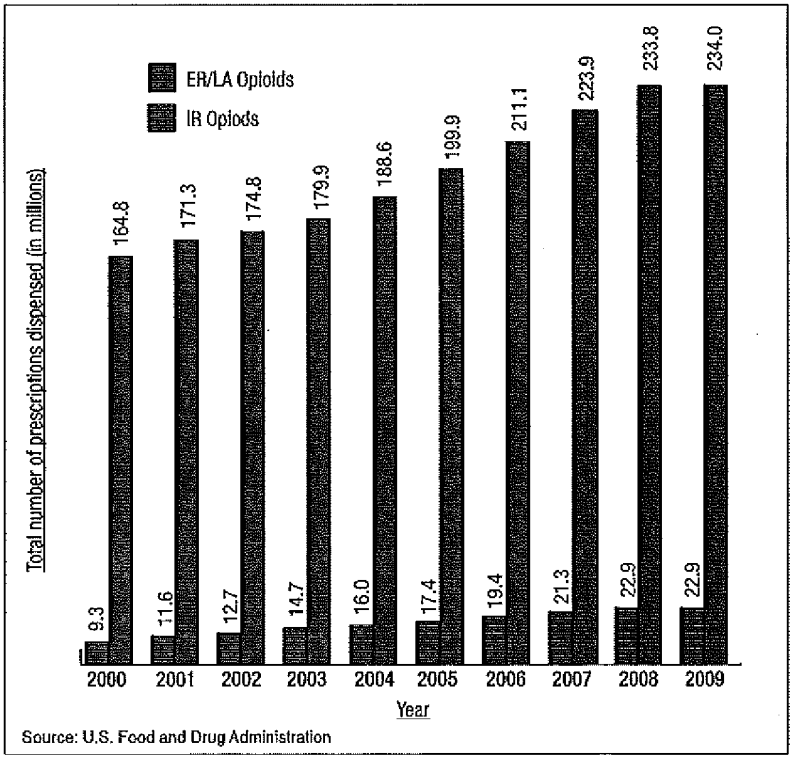
Pharmacists' responsibility in appropriate controlled substance dispensing

INTRODUCTION

Dispensing controlled substances in community pharmacies continues to increase as the number of opioid analgesic prescriptions has continued to grow steadily each year since 2000.[1] There was a slight reduction of these prescriptions reported in 2011 among teens, young adults ages 18 years to 25 years and workers' compensation claims.[2] This reduction may be related to more readily available consumer education and aggressive actions by federal, state and local officials to curb prescription drug abuse, particularly for opioid analgesics. The news, however, is not completely positive; prescriptions containing hydrocodone and acetaminophen in combination remained the most prescribed medications in the United States between 2007 and 2011. Prescriptions for products containing oxycodone as a single agent also increased in 2011 (Figure 1).

Oversight and authority of controlled substance prescribing and dispensing

Figure 1
Total number of prescriptions dispensed for ER/LA and IR opioids from U.S. outpatient retail pharmacies, 2000-2009



Source: U.S. Food and Drug Administration

is conducted by a combination of federal and state law enforcement, regulatory agencies and payers. The U.S. Drug Enforcement Administration, the agency with primary authority over regulation and oversight of controlled substances in the United States, places responsibility on both prescribers and pharmacists to ensure that prescriptions for controlled substances meet all legal requirements of a prescription and are appropriate for the condition prescribed. The pharmacist has both a professional and ethical responsibility to ensure appropriate dispensing and to reject invalid prescriptions. How should the pharmacist conduct the due diligence necessary for ensuring appropriate controlled substance prescriptions? Should the pharmacist simply assume that all opioid prescriptions are improper until proven otherwise? Certainly not; according to the DEA, the pharmacist must exercise "sound professional judgment" to determine the legitimacy of controlled substance prescriptions.[3] This lesson will provide the pharmacist with guidance regarding the current state of federal controlled substance legislation and regulation; an overview of actions in states and by third-party payers and other healthcare professionals to curb inappropriate prescribing and dispensing; and tools available to help the pharmacist make a sound professional judgment and perform due diligence when dispensing controlled substance prescriptions.

Part 1 will consider the pharmacist's responsibility and requirements performing the due diligence necessary to ensure appropriate dispensing of opioid prescriptions. Part 2 will examine partnerships among DEA and other government agencies, including the Office of National Drug Control Policy within the White House and the Food and Drug Administration; third-party insurers; the Medicare and Medicaid programs; and initiatives among healthcare professionals to ensure appropriate dispensing and prescribing. Finally, the lesson describes federal and state sanctions and disciplinary actions that may be taken against the pharmacist for failure to comply with controlled substance laws and regulations.

Before beginning the lesson, consider the actions or inactions taken by the pharmacist in Patient Scenario 1. This lesson will help the reader analyze the pharmacist's shortcomings in this scenario and will describe ways to improve in the future.

PART 1: THE PHARMACIST'S ROLE IN APPROPRIATE DISPENSING

Overview of types of fraudulent prescriptions

The DEA has provided a summary of the types of fraudulent prescriptions that the pharmacist may encounter. These include the following:

- Legitimate prescriptions with alterations made by a patient;
- Stolen prescription pads from a legiti-

PATIENT SCENARIO 1

A newly licensed pharmacist receives his first assignment in a community pharmacy. The company provides formal training to the pharmacist regarding company policies and procedures, and he also receives "informal" training from the pharmacist in charge, or PIC, regarding the pharmacy operations and customers. The PIC informs the new pharmacist that several very ill patients regularly receive controlled substance medications for managing chronic pain and that these patients should not cause alarm for the pharmacist when he receives their prescriptions. After his first month practicing, the pharmacist encounters one of the patients, J.M., and mentally notes that J.M. is one of the very old, frail and sick patients with cancer identified by the PIC. Each month, the patient presents a prescription for a supply of a Schedule II controlled substance that is filled by the pharmacist with no questions asked. During the new pharmacist's fourth month on the job, local law enforcement officials present themselves at the pharmacy with a warrant to search records related to J.M.'s prescriptions. They tell the pharmacist that they have a reasonable basis to conclude that all of his narcotic prescriptions dating back approximately one year were fraudulent and that he used several pharmacies to receive the same prescription medication. The new pharmacist is shocked at this revelation and the ensuing information that he learns during the investigation. In reviewing hard copy prescription records, it is apparent that the handwriting on prescriptions from more than a year ago "written by the same doctor" is completely different from the prescriptions in question, and upon further investigation into the pharmacy's database, the patient paid cash for certain prescriptions while others were covered by a third party.

Discussion

Consider the issues presented by this case. Did the pharmacist conduct appropriate due diligence in filling prescriptions, or does the PIC's word regarding several patients' condition suffice? Did the pharmacist behave unethically? What other steps could the pharmacist and pharmacy staff have taken to ensure the validity of the prescriptions? Was the pharmacist wrong in assuming that a sick, frail patient would automatically present valid prescriptions? Should the pharmacist question every prescription going forward?

The pharmacist should review this case prior to beginning the lesson and consider the action or inaction by the pharmacist in question. What issues does the pharmacist see in this scenario? Then, after reviewing Part 1 of the lesson, how should the pharmacist apply this information to scenario one?

The pharmacist should not have simply taken another pharmacist's word for the status of the patients. While both pharmacists have put the health of the pharmacy's patients first, the pharmacist should have taken additional steps to verify the prescription. While in this case, the pharmacist might not have immediately concluded that a call to the prescriber was necessary, he had a reasonable basis to review a prescription monitoring program database if available in the state. Further, he could have reviewed the prescriptions as entered in the pharmacy's database and determined the inconsistent payment methodology — as some paid by cash, while some paid by a third party. These actions might have then prompted the pharmacist to contact the prescriber for verification.

Table 1
Criteria to determine appropriate controlled substance prescriptions[4, 14]

PRESCRIBER CONSIDERATIONS
• Consider whether the prescriber writes for a quantity or prescribes controlled substances with more frequency than others in the area; • Consider whether the prescriber writes prescriptions for depressants, (e.g., benzodiazepines/ barbiturates) or stimulants (e.g., methamphetamine) in conjunction with narcotic analgesics. Drug abusers often request "uppers" and "downers" at the same time; and • Consider whether a number of patients appear at the pharmacy within a short period of time with the same or similar controlled substance prescriptions from a single prescriber.
PATIENT CONSIDERATIONS
• Review patient's history in PMP if available in the state; • Query the patient about his medical history and the need for the medication; • Consider the frequency that the patient receives the opioid analgesic; • Consider whether the patient receives prescriptions from a number of prescribers and uses different prescribers for noncontrolled substances; • Consider whether the patient pays cash for narcotic prescriptions while receiving others through insurance; • Consider whether the patient insists on brand name narcotics because these often have a greater street value compared to generics because of name recognition; and • Question prescriptions that suddenly appear from individuals who are not usual customers or who do not live in the community or area around your pharmacy.
CHARACTERISTICS OF POTENTIALLY FORGED PRESCRIPTIONS REQUIRING FOLLOW-UP BY PHARMACISTS TO PRESCRIBERS
• Quantities, directions or dosages appear different from usual medical usage; • Prescription does not use standard medical abbreviations for directions, dosages or names of medication; • Photocopied prescriptions; and • Prescriptions written in different colors or inks with different handwriting

mate prescriber, but with a different contact phone number;
- Drug seekers who phone in their own prescriptions and use their own phone number for verification;
- Drug abusers who use stolen pads to write prescriptions for fictitious patients; and,
- Individuals who present in emergency rooms for the purpose of obtaining a controlled substance prescription and then alter or copy the prescription for re-use.[3]

Table 1 provides an overview of criteria to determine whether a controlled substance prescription is appropriate and some key factors to consider when receiving a prescription or when a patient presents a prescription.[4]

DEA's corresponding responsibility doctrine and the pharmacist

The United States Controlled Substances Act is the statutory basis for federal oversight of controlled substance regulation in the United States. The CSA provides the pharmacist affirmative obligation to only fill prescriptions that are "issued in the usual course of professional treatment," and prescriptions that do not meet this requirement are considered improper.[5] This means that appropriate prescribing and dispensing is a two-way street: the pharmacist may be subjected to penalties under the provisions of the CSA for invalid prescriptions. The pharmacist must exercise sound professional judgment regarding the validity of a prescription prior to dispensing. The pharmacist should not assume that every controlled substance prescription is improper, but rather take affirmative steps to ensure the prescription's validity.

Steps the pharmacist must take to ensure the validity of controlled substance prescriptions

1. Ensure that only state-authorized prescribers write/order prescriptions. The DEA defines a practitioner as a physician, dentist, podiatrist, veterinarian, mid-level practitioner or other state-registered practitioner.[3] Individual states may more specifically define practitioners who can prescribe controlled substance prescriptions and the controlled substance schedules they may prescribe. Some states require that certain practitioners, such as physician assistants and nurse practitioners, only write prescriptions pursuant under a protocol with a doctor of medicine or doctor of osteopathy, while others permit greater autonomy for mid-level practitioners. The pharmacist must know the laws in each state where he or she practices and must verify the laws in other states if presented with a prescription from that state.

If the pharmacist is presented with a questionable prescription, he or she must take affirmative steps to verify the identity of the prescriber. If the pharmacist has questions, he or she may not want to use the contact information on the prescription, but rather use an independent source of contact information for the prescriber's office, such as a phone book or an Internet site. A telephone call may add a small amount of time to the dispensing process but is worth the effort for both the pharmacist's peace of mind as well as legal requirements.

2. Ensure prescription is written in the usual course of professional treatment. States have the authority to determine the scope of treatment by prescribers. States may restrict the ability of certain practitioners to write prescriptions only for certain indications or specific conditions — for example, dentists being restricted to treatments related to oral health. The DEA does not generally require prescribers to conduct in-person examinations, but requires that prescriptions be issued pursuant to a valid prescriber-patient relationship.[3] However, the pharmacist must comply with state laws and regulations related to the definition of a valid prescriber-patient relationship, including whether an in-person examination is required, how often an examination is required, and whether the state restricts prescribers from ordering for friends or family members. If the pharmacist has questions regarding whether a valid prescriber-patient relationship exists, he or she may contact the prescriber or ask the patient when they last saw the prescriber, or ask other general questions related to the interaction with the prescriber.

3. Verify prescriber DEA registration. Most pharmacists must commit to memory during pharmacy school the equation used to calculate a valid DEA registration of a prescriber. This equation is outlined in Table 2.[7]

The pharmacist must also understand federal and state requirements for prescribers who practice in hospital settings, and any other state requirements regarding additional numbers required for mid-level practitioners. Verifying the DEA registration using the formula and ensuring compliance with state laws and regulations provides a good start to ensuring appropriate prescriptions, but the pharmacist would be better served to verify the validity of the DEA registration with an independent source. After all, pharmacists are not the only people who know the formula for creating a DEA number, and forgers may create fictitious DEA registrations. The best direct source to verify a DEA registration is through the National Technical Service Information, or

Table 2
Formula to validate DEA registration[7]

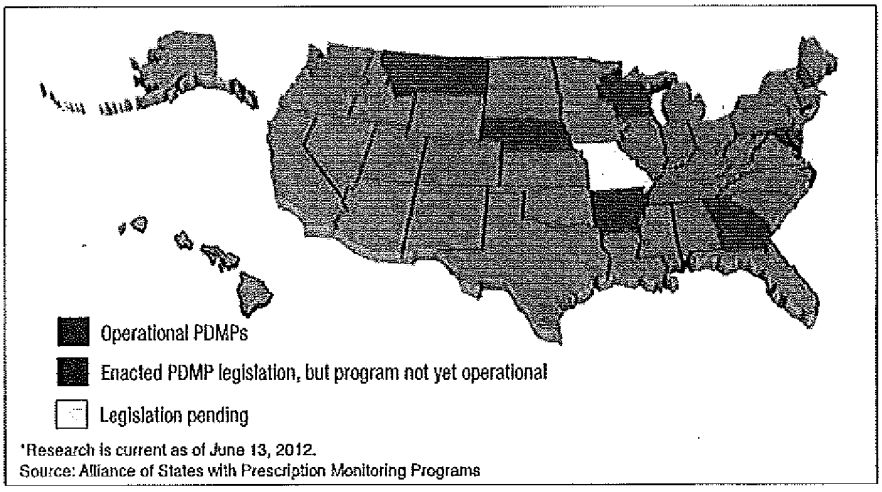
UNDERSTANDING DEA REGISTRATION NUMBERS

The DEA registration number is encoded by two alphabetical letters followed by a seven digit number. The first letter represents the registration code to designate the type of practitioner:
- A/B/F represents MDs, DOs, dentists and veterinarians;
- M represents mid-level practitioners, including physician assistants, nurse practitioners, nurse mid-wives and other mid-level practitioners recognized by state law; and
- The second letter is always the first letter of the practitioner's last name.

STEPS TO VERIFY DEA REGISTRATION

1. Add the first, third and fifth digits of the DEA number.
2. Add the second, fourth and sixth digits of the DEA number.
3. Multiply the result of Step 2 by two.
4. Add the result of Step 1 to the result of Step 3.
5. The last digit of this sum must be the same as the last digit of the DEA number.

Figure 2
Status of prescription drug monitoring programs



*Research is current as of June 13, 2012.
Source: Alliance of States with Prescription Monitoring Programs

NTIS, database, the official clearinghouse for government-related technical information. The NTIS database is available as a single purchase, or as a monthly or quarterly subscription by calling (800) 363-2068 or visiting www.ntis.gov/product/dea.htm. Most private entities that offer DEA verification will receive information through the NTIS database. DEA does not verify registration information. As a result, the pharmacist should refrain from contacting the local or national DEA field office for this information. If the pharmacist has questions regarding the pharmacy's access to databases to verify prescribers, he or she should contact the pharmacy owner(s) or manager(s).

4. Access information related to the prescriber or patient within a state's prescription monitoring program, or PMP, if available. Currently 48 of the 50 states have PMP programs to track controlled substances dispensed by pharmacies. Estimates, however, suggest that less than 40 states' programs are fully functional.[9] Figure 2 outlines PMP program status by state.[8]

The PMP systems generally track every controlled substance dispensed in the state and include such comprehensive information as the patient name, controlled substance name and quantity, date dispensed, prescriber and pharmacy identity.[9]

The pharmacist has varying degrees of access to the PMP data, and in some states, must obtain specific authorization to access the information. In other states, a notice in the pharmacy is sufficient in lieu of specific written authorization for access. The pharmacist must be judicious in accessing information in the PMP, particularly in those states where specific patient authorization is not necessary. The pharmacist must never abuse the privilege of reviewing the information in the database. The pharmacist should access information only when a prescription is presented, or the pharmacist is notified of a potential issue with a patient or prescriber. The pharmacist must always adhere to federal and state privacy and security laws, and act in a professional, ethical manner.

5. Review the entire prescription order. The pharmacist must take the time to comprehensively review the prescription order the patient presents. The pharmacist may conduct the following review steps in any order, although many pharmacy organizations have policies that require a check in a specified manner. The following is a suggested format for the pharmacist.

- **Review the prescription order for any changes or alterations.** Both handwritten and computer-generated prescriptions are subject to alteration. The pharmacist should first consider whether the prescription appears to be a photocopy that might indicate duplication of the original order by the patient. The pharmacist should specifically examine the date of the order to ensure that no changes have been made; then, the pharmacist should review the quantity and strength; and, the pharmacist should review the signature on the prescription order to ensure that the prescriber's handwritten signature is included on the prescription as required by the DEA.[3] Any alterations must be brought to the attention of the prescriber, and the pharmacist should not fill the prescription. In the case of Schedule III-V medications, a pharmacist may contact the prescriber to authorize a verbal telephone order for prescriptions that are improper as written. The pharmacist may not receive oral authorization for a Schedule II controlled substance prescription. DEA defers to state laws with regard to changes that a pharmacist may make on a Schedule II controlled substance prescription prior to filling.[10]
- **Obtain treatment plan and/or patient contract.** If customers are submitting prescriptions for large quantities of controlled substances (e.g., more than 100 dosage units per prescription or multiple controlled substance prescriptions), the pharmacist should request a copy of the customer's treatment plan and/or patient contract from either the customer or the prescribing physician that is maintained in the customer's file so that the pharmacist can ensure that the use of pain medication is being utilized to treat a valid medical condition in coordination with other protocols (i.e., physical therapy, etc.).
- **Review the date issued.** The DEA requires that prescriptions orders be written on the date that the person is seen by the physician and may not be pre- or post-dated.[3] If the prescription is dated for a future date when presented to the pharmacist, then the prescription is not valid and may not be filled. If the prescription has a date earlier than the day a person presents at the pharmacy, this might be cause for the pharmacist to conduct further due diligence regarding the prescription. The pharmacist must understand state laws and regulations related to prescription issuance date. The pharmacist may be surprised to learn that the DEA does not impose a time-limit for filling controlled substance prescriptions, even for Schedule II controlled substances. However, many states do.[3] The pharmacist may reasonably expect that some prescriptions may be issued in the days before the patient's pharmacy visit. For example, perhaps the patient is filling a prescription for a future procedure, or the patient may already have a supply of the medication at home. However, the pharmacist would be reasonably expected to question a prescription issued months before presentation at the pharmacy, even if the time frame falls within state regulations.
- **Review the medication, strength, dosage form and quantity.** This part of the review may be challenging for the pharmacist because it may require subjective judgment. Prescriptions for high dosages of narcotic medications are not necessarily fraudulent, and the pharmacist must ensure they consider the patient's entire condition and history before determining appropriateness. Currently, the FDA does not impose daily dosing limits on opioids, making it difficult for the pharmacist to judge whether a dose is appropriate.[1] The pharmacist may use the FDA's guidance for maximum daily dosages of acetaminophen to determine whether combination products containing opioids and acetaminophen are appropriate. While the current FDA recommendation for maximum daily dosage for acetaminophen remains at 4 g per day, manufacturers of over-the-counter acetaminophen have begun to reduce the maximum daily dosage recommendations to 3.25 g for regular strength OTC acetaminophen (325 mg per tablet), and 3 g per day for the extra strength formulation (500 mg per tablet).[12, 13] The pharmacist, to the extent possible, should review the patient's entire prescription history and OTC drug use to determine whether the acetaminophen levels are exceeded because of the risk for potentially fatal liver injury. Acetaminophen is not an ingredient in every opioid analgesic, and therefore, the pharmacist should use other references and resources to ensure the prescription is proper. These tips and criteria have been identified in Table 1. The pharmacist should closely examine the days' supply. The DEA does not impose limits on the quantity that may be dispensed, but some states do impose limits that may vary among different controlled substance schedules. Furthermore, insurers often limit the day's supply to 30 days in a community pharmacy. As always, if the pharmacist has questions regarding the day's supply or other components of the prescription, they should always contact the prescriber.
- **State specific requirements for verifying controlled substance prescriptions.** Increasingly, states require the pharmacist to take additional steps, including identification checks and other means of verification prior to dispensing a controlled substance prescription.[6] The DEA does not currently require any specific identification checks or other processes prior to dispensing a prescription. The pharmacist must understand state requirements to ensure appropriate dispensing.
- **Document, document, document!** The

pharmacist regularly hears this mantra for many actions taken in the pharmacy, but documentation is even more important when verifying a controlled substance prescription. The pharmacist must document the steps they have taken to verify the prescription, including any calls to the prescriber(s), conversations with the patient, medication history review, and PMP access and review on the prescription itself or in the pharmacy management system. While documentation will not necessarily insulate the pharmacist from sanctions or discipline for improper dispensing, it may help both the pharmacist and pharmacy explain the rationale for dispensing and mitigate any sanctions that might occur. Reviewing the dose, strength and days' supply is often subjective, and the pharmacist must perform the best due diligence to ensure appropriate dispensing. Now, reconsider the facts of Patient Scenario 1. Considering the verification steps outlined, the pharmacist did not engage in the proper due diligence to ensure that prescription orders for the patient were appropriate. However, the pharmacist did not seem to act in an unethical manner. The pharmacist tried to act in the best interest of an ill patient, but unfortunately, this does not suggest his actions were proper. The pharmacist should have taken further action to verify the prescriptions. Based on this scenario, what actions should a pharmacist take when confronted by a situation similar to the scenario or in other circumstances involving inappropriate prescribing?

After the due diligence: Steps the pharmacist should take if inappropriate prescribing occurs

The pharmacist may take a number of actions when he or she finds inappropriate prescribing. The actions often depend upon the nature of the inappropriate prescribing and require the pharmacist to use his or her professional judgment to determine the level of intervention necessary. As healthcare professionals, pharmacists have the right to deny filling prescriptions. However, states have differing laws and regulations when the pharmacist chooses not to fill prescriptions. In some cases, the pharmacist must record the rationale for the denial on the prescription and return it to the patient. Increasingly, states are taking more aggressive actions when the pharmacist affirmatively knows or has reasonable cause to know that a controlled substance prescription is fraudulent. For example, several states now require the pharmacist to retain the prescription and take actions to either submit it to law enforcement or maintain it in the pharmacy for a period of time prior to discarding.[6] For a single incident, the pharmacist should notify the pharmacy owner(s), manager(s) or the company's compliance officer. The pharmacist may not find it immediately necessary to contact local law enforcement or the DEA without first taking the appropriate steps through the pharmacy organization's management or legal teams. If, however, the pharmacist suspects a serious pattern of abuse by a prescriber or patient, or the pharmacy's management is not taking appropriate actions, he or she should call the DEA's abuse hotline at (877) RX-ABUSE or the regional field DEA office identified by visiting www.deadiversion.usdoj.gov/offices_n_dirs/fielddiv/index.html, or contact local law enforcement personnel.

Pharmacy controls to ensure appropriate controlled substance dispensing

The pharmacist should take the following actions to prevent widespread prescription drug abuse and ensure appropriate controlled substance dispensing in the pharmacy.

- Identify area prescribers who most often prescribe narcotic prescriptions and review these prescriptions carefully. This process must be conducted in a judicious and professional manner. This process should not automatically implicate prescribers or patients simply on the basis of narcotic prescribing or the number of prescriptions, but rather should simply be a process to flag prescriptions that may require additional scrutiny. Communication by the pharmacist to both the prescriber and patient is necessary because it may uncover rational reasons for prescribing or use of controlled substances. Once the pharmacist identifies the prescribers and patients who should be flagged, the pharmacist and pharmacy staff must ensure that all federal and state privacy laws and regulations, and other protections, are maintained when doing so.
- The pharmacist should acquaint himself or herself with controlled substances that are subject to diversion in their area and provide this information to all pharmacy personnel.[14]
- The pharmacist should also implement a controlled substance order management and inventory system to closely monitor receipt and dispensing of controlled substances. The pharmacist should review logbooks, perpetual inventory, invoices, receipts and other pharmacy distribution records to flag excessive ordering or dispensing by certain pharmacists or on certain shifts. The DEA and law enforcement do not simply focus on prescriptions, but also on controlled substance ordering practices and patterns by pharmacies.

Given the steps outlined to identify inap-

PATIENT SCENARIO 2

A patient, T.J., presents a Schedule II narcotic prescription at a chain pharmacy with a high prescription volume and a transient patient population. When T.J. gives the prescription to the pharmacy technician, she says that she has never filled prescriptions at this pharmacy location or at any of the pharmacy chain's other locations. T.J. looks for her third party prescription card and realizes that she forgot it. She then asks the pharmacy technician whether she may use her medical insurance card and a photo identification to access her insurance prescription drug benefits. The pharmacy technician takes the prescription and the insurance card to the pharmacist. The pharmacist reviews the prescription and the insurance card, looks at the patient and then verbally communicates information to the pharmacy technician. The pharmacy technician then returned and notified T.J. that the medication was not in stock.

Discussion

In this case, did the pharmacy personnel act appropriately in denying the prescription? Did the pharmacy staff jump to inappropriate conclusions without performing due diligence? Should the fact that T.J. never filled prescriptions at this pharmacy or the pharmacy chain alone be evidence of an improper prescription? Does the pharmacy's location in a high-volume, high-traffic, transient area make a difference, and should it? Is the lack of presenting a prescription insurance card evidence of an improper prescription? What steps could the pharmacy staff have taken to help the patient fill this prescription?

The pharmacist seems to be in a challenging position in this scenario. It seems as though the pharmacist might be exhibiting a bit of reasonable suspicion, given the location of the pharmacy in a high-traffic and transient area, where the pharmacist does not know the patients well. However, the pharmacist's actions in this case could be considered unreasonable because there is no evidence that the patient requested that she pay in cash rather than billing a third party, and she willingly gave her medical insurance card to the technician. Further, the fact that the patient has never filled prescriptions in the pharmacy or at any other store in the chain does not necessarily suggest a fraudulent controlled substance prescription. If the pharmacist had concerns or questions, he could have reviewed information in a PMP, if available, or contacted the prescriber directly. Pharmacists must be careful not to make assumptions about a patient or a prescription without utilizing resources available to verify prescription information. While this is sometimes easier said than done, it gives the pharmacist peace of mind, ensures compliance with regulations and helps to ensure that patients receive appropriate medications.

propriate prescribing or potentially fraudulent prescriptions and those listed to ensure appropriate controlled substance dispensing within a pharmacy, consider Patient Scenario 2, and determine whether the pharmacist and pharmacy personnel acted properly in rejecting a prescription.

In the end, the determination of a proper prescription is not a bright line test, but the pharmacist may take affirmative steps to conduct due diligence to make an appropriate determination. The pharmacist must know that they are not alone in efforts to uncover improper dispensing. The DEA, other federal agencies, third-party insurance payers and other healthcare professionals also are partners with pharmacies to ensure those patients who require opioid analgesics receive them while reducing inappropriate prescribing and dispensing. Before moving to Part 2, the pharmacist may want to review Table 3, which provides a checklist to help the pharmacist establish pharmacy policies and procedures for appropriate opioid dispensing. Table 4 lists resources to aid in this process.

Table 3
Checklist of policies and procedures to ensure appropriate controlled substances and resources for pharmacists[3-6,14-15,19]

POLICIES AND PROCEDURES FOR THE PHARMACIST
• Understand the DEA laws and regulations for pharmacists and pharmacies and any unique state laws or regulations; • Know area prescribers and patients: Identify potential problems with prescribing or use, and communicate with pharmacy personnel. Always ensure compliance with federal and state privacy laws and proceed ethically. Communicate with prescribers regarding concerns or inappropriate prescribing; • Engage in active outreach to consumers in your area regarding appropriate controlled substance use: - Ensure proper storage of controlled substances in the home, keeping them out of reach of children; - Protect controlled substances in the home from theft; - Discuss issues related to overdose, toxicity, driving and use with other legal and illegal controlled substances and alcohol; - Never share controlled substances with others, and always comply with written order; - Discuss issues associated with pain management protocols; and - Provide information related to safe disposal and National Takeback Days (information available at AWARERx website, www.awarerx.org/main.php); • Know the potential medications abused in your area, including any related street slang, and develop policies to flag and manage prescriptions; • Educate all pharmacy personnel on appropriate opioid use and signs of drug seeking behavior or abuse. Nonpharmacist personnel must be trained on policies and procedures to report potential issues. Pharmacists, pharmacy management and pharmacy owners must develop written policies and procedures for managing situations of suspected misuse or abuse of controlled substances; • Ensure that the pharmacist verifies all controlled substance prescriptions: - Is it written by a state-authorized prescriber in the usual course of professional treatment?; - Verify the DEA registration; - Use PMPs, contact third-party payers with questions about the patient's other medications, review treatment and/or medication agreements, or ensure compliance with other state mandates, such as identification checks; - Review the entire prescription order: - Check for alterations and differences in ink; - Review date issued (no pre- or post-dating); and - Review name, strength, quantity and dosing. Contact the prescriber with questions, and do not always assume excessive doses are forged prescriptions; - Document any follow-up and interventions made with prescribers, patients, PMPs or third-party plans; • Establish policies and procedures for the pharmacist and pharmacy personnel to follow when inappropriate opioid use occurs, including when to contact pharmacy manager(s) or owner(s), the DEA or local law enforcement: - Conspicuously post contact information for the local DEA office, law enforcement and DEA's Rx abuse hotline (877-Rx-ABUSE); and • Ensure that all policies and procedures are in writing, and pharmacists and other personnel receive periodic training and education. Don't just shelve policies and procedures in a manual.

Table 4
Resources for pharmacists and pharmacies

RESOURCE	WEBSITE
DEA Pharmacist's Manual, a necessity for every pharmacy	www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf
Your local DEA office	www.deadiversion.usdoj.gov/offices_n_dirs/fielddiv/index.html
DEA Office of Diversion Control website (includes all DEA laws and regulations and other information for healthcare professionals, manufacturers and distributors)	www.deadiversion.usdoj.gov/
Information about PMPs	www.deadiversion.usdoj.gov/faq/rx_monitor.htm, pmpalliance.org/
Pharmacy Today REMS article	lmlrus.com/tmp/6063/7479/1001/pm6063.pdf
State-by-state information from the boards of pharmacy is available by purchasing the *Survey of Pharmacy Law* ($195) from NABP	nabp.net/publications/survey-of-pharmacy-law/
Information about REMS for long-acting and extended release opioids	fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm309742.htm
Visit AWARERx by the National Association of Boards of Pharmacy for updates and emails regarding enforcement actions and trends in diversion and inappropriate drug distribution	awarerx.org/main.php

PART 2: OTHER FEDERAL AGENCIES AND PAYER EFFORTS TO REDUCE INAPPROPRIATE CONTROLLED SUBSTANCE PRESCRIBING

The pharmacist must understand the core DEA and state board of pharmacy laws and regulations governing controlled substance prescribing and dispensing, and they also must understand efforts by other federal agencies and third-party payers, including pharmacy benefit management companies and the Medicare and Medicaid programs, to curb inappropriate controlled substance prescribing and utilization. In reviewing this information, the pharmacist should consider the intersection and applicability of these efforts in their daily practice.

General trends in federal efforts to ensure controlled substance dispensing and prescribing

The DEA is the primary federal agency with oversight over controlled substance dispensing, prescribing and distribution in the United States. However, recent increases in prescription opioid use and abuse have led to a more comprehensive approach to curb misuse and abuse of controlled substances. The pharmacist must understand the parallel efforts by the ONDCP and the FDA as part of a comprehensive federal government effort.

ONDCP efforts to curb controlled substance abuse in the United States

ONDCP, located within the White House, drafted a Prescription Drug Abuse Prevention Plan in 2011 to begin an "all hands on deck" coordinated federal government agency effort to maximize legitimate use of prescription drugs while minimizing abuse and ensuring access to effective drug abuse treatment programs.[15] The plan includes the following key elements that will help pharmacists, prescribers and patients partner to achieve more appropriate medication utilization:

- Educational efforts to improve training by prescribers and pharmacists on narcotic addiction, adverse effects and diversion. These efforts will include partnerships

Pharmacist CE LESSON

Table 5
ER/LA Opioids subject to FDA REMS[23]

TRADE NAME	GENERIC NAME	COMPANY	CONTACT
BRAND NAME PRODUCTS			
Avinza®	Morphine sulfate extended-release capsules	Pfizer	(800) 438-1985
Butrans®	Buprenorphine transdermal system	Purdue Pharma	(888) 726-7535
Dolophine®	Methadone hydrochloride tablets	Roxane Laboratories	(800) 962-8364
Duragesic®	Fentanyl transdermal system	Janssen Pharmaceuticals	(800) 526-7736
Embeda®***	Morphine sulfate and naltrexone extended-release capsules	Pfizer	(800) 438-1985
EXALGO®	Hydromorphone hydrochloride extended-release tablets	Mallinckrodt	(800) 778-7898
Kadian®	Morphine sulfate extended-release capsules	Actavis	(888) 496-3082
Methadose™	Methadone hydrochloride tablets	Mallinckrodt	(800) 778-7898
MS Contin®	Morphine sulfate controlled-release tablets	Purdue Pharma	(888) 726-7535
Nucynta® ER	Tapentadol extended-release oral tablets	Janssen Pharmaceuticals	(800) 526-7736
Opana® ER	Oxymorphone hydrochloride extended-release tablets	Endo Pharmaceuticals	(800) 462-3636
OxyContin®	Oxycodone hydrochloride controlled-release tablets	Purdue Pharma	(888) 726-7535
Palladone®*	Hydromorphone hydrochloride extended-release capsules	Purdue Pharma	(888) 726-7535
GENERIC PRODUCTS			
Fentanyl	Fentanyl extended-release transdermal system	Actavis	(877) 422-7452
Fentanyl	Fentanyl extended-release transdermal system	Mallinckrodt	(800) 778-7898
Fentanyl	Fentanyl extended-release transdermal system	Mylan Technologies	(877) 446-3679
Fentanyl	Fentanyl extended-release transdermal system	Noven Pharmaceuticals (marketed by Apotex)	(800) 667-4708
Fentanyl	Fentanyl extended-release transdermal system	Sandoz	(800) 525-8747
Fentanyl	Fentanyl transdermal system	Watson Laboratories	(800) 272-5525
Methadone Hydrochloride	Methadone hydrochloride tablets	Mallinckrodt	(800) 778-7898
Methadone Hydrochloride	Methadone hydrochloride tablets	Roxane Laboratories	(800) 962-8364
Methadone Hydrochloride	Methadone hydrochloride Intensol™ oral concentrate	Roxane Laboratories	(800) 962-8364
Methadone Hydrochloride	Methadone hydrochloride oral solution	Roxane Laboratories	(800) 962-8364
Methadone Hydrochloride	Methadone hydrochloride tablets	Sandoz	(800) 525-8747
Methadone Hydrochloride	Methadone hydrochloride tablets	ThePharmaNetwork	(877) 272-7901
Methadone Hydrochloride	Methadone hydrochloride oral solution	VistaPharm	(727) 530-1633
Morphine Sulfate	Morphine sulfate extended-release tablets	Vintage Pharmaceuticals, d/b/a Qualitest Pharmaceuticals	(800) 444-4011
Morphine Sulfate	Morphine sulfate extended-release tablets	Mallinckrodt	(800) 778-7898
Morphine Sulfate	Morphine sulfate extended-release tablets	Mylan Pharmaceuticals	(877) 446-3679
Morphine Sulfate	Morphine sulfate extended-release tablets	Rhodes Pharmaceuticals	(888) 827-0616
Morphine Sulfate	Morphine sulfate extended-release capsules	Watson Laboratories	(800) 272-5525
Oxycodone Hydrochloride	Oxycodone hydrochloride extended-release tablets**	Vintage Pharmaceuticals, d/b/a Qualitest Pharmaceuticals	(800) 444-4011
Oxycodone Hydrochloride	Oxycodone hydrochloride extended-release tablets**	Mallinckrodt	(800) 778-7898
Oxymorphone Hydrochloride	Oxymorphone hydrochloride extended-release tablets	Actavis	(800) 432-8534
Oxymorphone Hydrochloride	Oxymorphone hydrochloride extended-release tablets	Impax (marketed by Global Pharmaceuticals)	(800) 934-6729

*No longer being marketed, but is still approved
**Tentatively approved products
***Not currently available or marketed due to a voluntary recall, but is still approved

with the FDA (described later), pharmaceutical manufacturers and health professional schools to provide educational programs and disseminate information related to narcotic abuse. These efforts also will extend to educational campaigns designed for consumers to increase awareness of prescription drug use and misuse.

Community pharmacies will play a key role in consumer education efforts. The pharmacist may wish to consider creating a resource that could be provided to pa-

tients on addiction treatment and recovery services in their community.[15]

- Improve tracking and monitoring through increased and improved use of PMPs, and to further combine federal, state and local efforts, including identifying financial resources to assist with achieving the stated goals. Specific goals include evaluating programs that restrict patients who doctor shop and abuse prescription drugs to a single pharmacy and prescriber, and use of health information technology, including electronic health records and health information exchanges to improve tracking and monitoring. The government also seeks to increase funding for PMPs and other tools implemented by states and healthcare professionals to curb inappropriate controlled substance use. These efforts coincide with the National Association of Boards of Pharmacy's initiative to securely interconnect state PMP databases to allow states to share information on controlled substance prescriptions. Currently, 10 states use NABP's interconnectivity initiative to share information: Arizona, Connecticut, Indiana, Kansas, Michigan, New Mexico, North Dakota, Ohio, North Carolina and Virginia.[17] In 2013, 25 states are expected to participate in the NABP initiative.[17]
- Increase enforcement actions against prescribers who prescribe outside the course of professional practice or for illegitimate purposes and to reduce patient abuses, particularly doctor shopping. Efforts in this area include aggressive enforcement action against inappropriate prescribing in pain management clinics and development of model laws and regulations for pain management clinics in states — including penalties and disciplinary procedures. The model regulations may be incorporated by state medical, pharmacy and nursing boards to improve practices within a state.

FDA risk evaluation and mitigation strategy for extended-release and long-acting opioid analgesics

A 2007 federal law, the Food and Drug Administration Amendments Act, established REMS, a legal tool for manufacturers and the FDA to utilize when medications pose a significant risk of harm when used by certain individuals, but also provide enough clinical effect to continue marketing.[18] The general purpose of REMS is for the FDA and pharmaceutical manufacturers to work together to implement a more aggressive approach to managing the post-marketing surveillance process and to take the additional steps that may be necessary to ensure safe use of marketed prescription drugs.[19] If the FDA identifies a product requiring REMS, the manufacturer must then develop a program with agreed upon components that may include:

- Medication guide;
- Communication plan;
- Elements to assure safe and effective use, including any of the following:
  - Training/certification of prescribers;
  - Training/certification of pharmacists/pharmacies;
  - Restrictions on where drug is dispensed;
  - Evidence of patient safe use conditions;
  - Patient monitoring; and
  - Enrollment of patient in a registry;
- Implementation system for the elements to assure safe use; and
- Timetable for assessing the plan's effectiveness, usually at 18 months, three years and seven years.[20]

Over a three-year period, the FDA, pharmaceutical industry stakeholders, pain management and addiction advocacy groups, and healthcare professionals debated the issue of implementing a REMS for the entire spectrum of opioid analgesics, but concluded that the extended-release and long-acting opioids are extensively misprescribed, misused and abused — leading to overdoses, addiction and deaths — and therefore are in need of additional scrutiny and oversight.[21] According to the FDA, in 2007 more than 33 million Americans age 12 years and older misused ER/LA opioids, and 12,000 of 28,000 deaths associated with medication use involved use or misuse of opioids either prescribed for them or obtained illegally.[22] The debate surrounding the misuse and abuse of opioid analgesics coincided with ONDCP's release of its plan to curb prescription drug abuse. As a result, beginning in July 2012, manufacturers of certain ER/LA products are required to implement new safety requirements to assure safe use.[21] The opioid REMS includes 30 products containing ER/LA versions of hydromorphone, morphine, oxycodone, oxymorphone, tapentadol, and fentanyl- and buprenorphine-containing transdermal delivery systems manufactured or distributed by 20 companies.[21] They are listed by branded products and generic products in Table 5.

The ER/LA REMS includes required elements to assure safe use: prescriber training; an updated medication guide for consumers outlining the risks of opioid misuse and abuse; patient counseling; and assessment and auditing. Currently, the continuing education requirements for prescribers are voluntary and will begin in March 2013.[20] The pharmacist will be responsible for providing the updated medication guide to the patient. The medication guide must be provided either directly by the manufacturer or distributor with the delivery of the professionally packaged products to the pharmacy, or the manufacturer must provide instructions to the pharmacy on how to obtain the medication guide. Pharmacies that fail to provide a required medication guide may be subject to FDA misbranding sanctions, including penalties of $250,000 to $1 million per incident.[19] By implementing the opioid REMS program, the FDA believes it can better partner with healthcare professionals and the pharmaceutical industry to reduce opioid misuse and abuse and provide a better understanding of appropriate uses of narcotic agents.

Health plan, payer, and healthcare clinic and prescriber office initiatives to improve opioid use

Health plans and third party payers, including PBMs, often receive extensive and comprehensive information related to a patient, including health records outlining chronic conditions that may require pain management and the medications used for these conditions. According to statistics cited by one PBM, pharmacy costs for abusers of opioid medications are five to seven times greater than non-abusers, and emergency department visits among opioid abusers are more than two times greater than non-abusers.[23] For these reasons, health plans and payers must partner with healthcare professionals to reduce opioid misuse and abuse. Health plans and payers include private health insurers for the self-insured, employer, small group and individual markets, as well as the Medicare Part D program, state Medicaid programs and Medicaid managed care plans. The pharmacist should be familiar with current trends among payers and then work directly with specific plans as needed. A growing trend among healthcare clinics and prescriber offices is to enter into a "medication agreement" to promote more appropriate use. More detail on these initiatives follows.

- **Initiatives by private health plans and PBMs:** A growing number of health plans and PBMs now provide prescribers with profiles of patients at high-risk for opioid misuse and abuse. This profile may include a patient's complete medication history and a list of pharmacies where prescriptions are filled. This profile goes beyond the more traditional utilization management tools programmed in pharmacy management computer systems that are initiated prior to dispensing a prescription. Health plans serving commercial populations have much more flexibility than Medicare Part D plans to restrict high-risk patients from receiving opioid agents at the point of sale. High-risk users may be identified by the number of prescriptions obtained over a period of time, receipt of opioids from a number of prescribers and receipt of prescriptions from multiple locations and pharmacies. This proactive approach allows prescribers to directly review a patient's history and reduce the potential for inappropriate prescribing or duplicate therapy. Other PBMs engage in

provider-focused education, clinical support and formulary management. Some plans provide clinical pharmacists access to prescribers for discussion, consultation and case management.[23]

- **Initiatives by Medicare Part D plans:** Beginning in 2013, Medicare Part D will require more aggressive interventions by plans to reduce inappropriate prescribing of opioids and other medications.[11] Plans also will be subject to increased scrutiny, oversight and penalties by CMS for failure to implement effective controls.[11] As Medicare Part D plans enhance programs to curb controlled substance misuse and abuse, private health plans and PBMs will likely follow. CMS' goal is to ensure that patients are not denied opioid analgesics at the point of sale in a community pharmacy, but rather that Part D plans implement system edits and communication plans to curb inappropriate prescribing. Required controls include:
  - **Improved use of concurrent claim edits for purposes of safety controls at point of sale.** Under Medicare Part D, plans may use FDA-recommended maximum daily dosage limits to reject claims for certain prescriptions. Opioids do not currently have an FDA-recommended maximum daily dosage limits, but the FDA recommends a maximum daily dosage of 4 g of acetaminophen that may be used as a basis to screen prescriptions at the point of sale. CMS has indicated that plans may conduct drug utilization review edits prior to dispensing a combination opioid product containing acetaminophen, and may deny prescriptions for early refills, therapeutic duplication and exceeding maximum dosing for acetaminophen levels.[11]
  - **Improved use of formulary utilization management** allows plans to implement quantity limits — including maximum days' supply — for single agent opioid products without acetaminophen. Plans must first seek approval by CMS to implement formulary management that places quantity limits on single agent opioids because the FDA does not currently place quantity limits on opioids and therefore, plans cannot implement controls to outright reject these agents at the point of sale.[11]
  - **Improved retrospective drug utilization review, or DUR, and case management** that rely on the use of DUR program edits and beneficiary clinical assessment based on the input of case managers and the pharmacy and therapeutics committee. This control is designed to help plans balance the subjective task of identifying individuals with chronic pain who require greater than usual doses of controlled substance medications compared to those who might be misusing or abusing these medications. Retrospective DUR programming adopted by the P&T committee allows plans to identify specific patterns of overutilization or potentially improper use, and then refer these patients to case managers.
- **Initiatives by Medicaid programs.** Medicaid programs, which are jointly administered by federal and state governments and also some managed care companies, will likely take a similar approach to private plans and Medicare Part D. The pharmacist should check with the states where they practice and the Medicaid managed care plans in their area for more insight. The pharmacist also should understand that since 2008, most Medicaid prescriptions for both DEA-controlled substances and non-controlled substances, with some exemptions, must be written on a "tamper-resistant prescription pad."[24] Pharmacists interested in learning more about the CMS directive issued in 2007 should visit: cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE0736.pdf. The pharmacist also should review other state requirements for controlled substance prescription blanks.
- **Voluntary medication use agreements by healthcare clinics and prescribers.** A growing trend among healthcare clinics and prescribers is to implement medication use agreements for patients who require long-term controlled substance use for their condition. The medication use agreement represents a bilateral contract between the prescriber and patient regarding the risks, benefits and appropriate uses of opioid agents. Additionally, the agreement outlines the responsibilities of both parties in appropriate utilization and prescribing. While these medication use agreements are not explicitly recognized by the DEA as a method to excuse inappropriate prescribing practices or abuses by patients, they may serve as documentation of reasonable efforts to ensure appropriate utilization. In some cases, the medication use agreement will outline standard treatment protocols and medications. These agreements may be shared with dispensing pharmacies and health plans to identify pain management protocols and expectations for dispensing. The agreements do not excuse inappropriate dispensing, but may be used as part of the documentation and due diligence process by the pharmacist and health plan.[25]

Disciplinary actions and sanctions against pharmacists for noncompliance with federal and state controlled substance regulations

The pharmacist may be subject to criminal monetary penalties by the DEA and also subject to disciplinary actions or loss of his or her license at the state level for violations related to controlled substance laws and regulations. The pharmacist also may be subject to federal and state criminal laws outside of the DEA and state board of pharmacy for controlled substance violations. DEA sanctions against pharmacists who fail to maintain records or dispense controlled substances in violation of CSA begin at $10,000. In a 2008 case, a pharmacist in Texas paid $600,000 — a record amount — to resolve issues related to excessive purchasing of certain controlled substances.[25] The pharmacist also must understand that state boards of pharmacy may revoke or suspend pharmacists' licenses for unprofessional conduct related to controlled substance management and dispensing even if they are not found guilty in a civil or criminal trial.[26]

CONCLUSION

The pharmacist has an important legal responsibility to appropriately dispense all prescriptions, but with increased federal and state oversight of controlled substances, the pharmacist must be hyper-vigilant when dispensing controlled substance prescriptions, particularly opioid products. The pharmacist must perform the proper due diligence prior to dispensing opioid prescriptions. Due diligence does not require that the pharmacist assume that every prescription is improper, but rather, by using their professional judgment, common sense and enacting the sample policies and procedures listed in Table 3, the pharmacist can help patients who require opioid prescriptions to receive them in a timely manner while reducing the number of inappropriate prescriptions dispensed.

FOR A COMPLETE LIST OF REFERENCES, VISIT WWW.CEDRUGSTORENEWS.COM

PRACTICE POINTS

This lesson will help the pharmacist gain insight into the following areas:

- Responsibilities of the pharmacist when dispensing controlled substance prescriptions
- A brief overview of the current federal/state relationship for oversight of controlled substance prescriptions
- Overview of the due diligence necessary for the pharmacist to fulfill his or her corresponding responsibility when filling a prescription
- Recognition of potentially fraudulent prescriptions or patient behavior that might suggest opioid abuse
- Tools and resources available to assist the pharmacist to appropriately dispense opioids

Pharmacist CE LESSON

Learning Assessment

Successful completion of "Pharmacists' responsibility in appropriate controlled substance dispensing" (401-000-12-012-H03-P) is worth two contact hours of credit. To submit answers, visit our website at www.CEdrugstorenews.com.

1. Which of the following represents the primary law in the United States that governs controlled substance regulation?
a. Food and Drug Administration Amendments Act of 2007
b. Controlled Substances Act
c. State boards of pharmacy have primary oversight, not the federal government
d. Office of National Drug Control Policy

2. Which of the following falls primarily under the jurisdiction of the Drug Enforcement Administration, and not the states?
a. Determining the types of practitioners who may prescribe controlled substances
b. Establishing a specific definition or course of professional treatment
c. Establishing a prescription monitoring program
d. Registering practitioners to prescribe controlled substances

3. If a pharmacist receives a single controlled substance prescription from a patient for a dosage level of a controlled substance that seems excessive, what is the best action for the pharmacist take?
a. Assume the prescription is forged.
b. Call local law enforcement, and report the patient.
c. Review the entire prescription, and contact the prescriber with questions.
d. Review the prescriber DEA registration database, and if valid, fill the prescription.

4. Which of the following statements is true?
a. The DEA imposes quantity limits on dosages for some controlled substance prescriptions.
b. The DEA imposes limits on the maximum daily dosage rates for controlled substance combination products containing acetaminophen.
c. The DEA imposes strict time frames on when a Schedule II controlled substance may be filled.
d. Prescriptions for controlled substances may not be pre-dated, but it is not necessarily a forged prescription if a patient presents it for filling a few days after the date prescribed.

5. If a pharmacist seeks to verify a prescriber's DEA registration, which of the following represents the best course of action to take:
a. Ask the patient directly
b. Contact the DEA directly
c. Utilize the National Technical Information Service database
d. Review the registration information on the prescription, and then perform the appropriate calculation

6. Which of the following correctly states the pharmacist's responsibility under the Food and Drug Administration's risk evaluation and mitigation strategies for long-acting and extended-release opioids?
a. Provide patients with an updated medication guide
b. Provide prescriber-training on appropriate controlled substance utilization
c. Take mandatory continuing education course on appropriate controlled substance dispensing and utilization
d. Document the number of opioid prescriptions dispensed in a month, and report it directly to the FDA

7. If the pharmacist fails to take the appropriate steps under the LA/ER REMS, what actions may be taken against him or her?
a. The pharmacist may be found guilty of an FDA misbranding violation.
b. The pharmacist is in violation of the Controlled Substances Act.
c. The pharmacist may only receive sanctions by the applicable state board of pharmacy and no other federal agency.
d. The pharmacist may be found guilty of adulterating the prescription.

8. A state has implemented a PMP for controlled substances and allows the pharmacist to access it at any time. Which of the following represents a proper situation for the pharmacist to access the PMP?
a. The pharmacist wants to see what medications his friend is taking.
b. The pharmacist believes that a group of prescribers may be inappropriately prescribing controlled substances for monetary gain.
c. A new pharmacist wants to get an idea of the controlled substances all of the pharmacy's patients are taking, so the pharmacist checks on all of them after he fills a prescription, whether it is a controlled substance or not.
d. The pharmacist does not like a prescriber and accesses the database as a means to use an excuse to not fill any controlled substance prescriptions written by him.

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9. Which of the following correctly states the role of the federal and state governments in overseeing controlled substance regulations in the United States?
a. DEA alone has authority over enforcing controlled substance regulations in the United States.
b. DEA generally has authority over enforcing controlled substance regulations in the United States, but defers completely to state boards of pharmacy for oversight over pharmacists.
c. DEA laws and regulations provide the basis for controlled substance regulation in the United States, but states may implement more stringent requirements on pharmacists and prescribers.
d. DEA often partners with other federal agencies, including the FDA, but state boards of pharmacy must only follow DEA directives in regard to pharmacists because the FDA has no authority over pharmacists and pharmacies.

10. Which of the following describes the relationship between third-party payers and pharmacists to ensure appropriate prescribing of controlled substances in the United States?
a. Third-party payers only pay claims sent by pharmacies and therefore have absolutely no role to play in ensuring appropriate controlled substance dispensing.
b. Third-party payers must always deny claims for excessive dosages of opioids sent by pharmacies.
c. Third-party payers must report inappropriate opioid prescriptions to FDA under the new REMS program.
d. Third-party payers may implement clinical and management tools to partner with pharmacists and pharmacies to ensure appropriate controlled substance prescribing, dispensing and utilization.

11. A patient with drug-seeking behavior may exhibit which of the following?
a.. Demand for brand name-only opioid prescriptions when generics are available
b. Present opioid prescriptions for multiple people at the same time
c. Pay cash for opioids when a third party covers other medications
d. All of the above

12. Which of the following represents the current stance on the maximum daily dosage of opioid analgesics?
a. A patient may receive 4 g/day of an opioid-containing product.
b. A patient may receive 3 g/day of an opioid-containing product.
c. The FDA currently does not limit the maximum daily dose of opioids
d. The FDA allows each manufacturer to establish a maximum daily dosage of opioids that must then be followed by health plans and pharmacies.

13. Using the calculation to determine appropriate DEA registration numbers, which of the following represents a valid registration for a medical doctor named Mary Jones?
a. MJ2233445
b. AJ2233445
c. BM2233445
d. AJ3456721

14. Which of the following is not an appropriate action for the pharmacist who seeks to reduce opioid misuse and abuse?
a. Communicate directly with patients and caregivers regarding the dangers of opioid misuse and abuse
b. Use MPs as a tool when questions arise regarding a patient's use of large quantities of an opioid
c. Avoid conversations with prescribers regarding issues with patient abuse of controlled substances because the prescriber alone is responsible for the patient's care
d. Review medication agreements to determine expectations for a patient's opioid treatment regimens

15. Which of the following does the DEA require of pharmacists who fill controlled substance prescriptions?
a. Notification that the pharmacist has reviewed any applicable medication agreement.
b. The pharmacist must use sound professional judgment to determine the legitimacy of prescriptions.
c. The pharmacist must ensure that he or she knows the patient's diagnosis prior to dispensing an opioid agent.
d. The pharmacist must ensure that the patient received an actual physical exam prior to filling any controlled substance prescription.

16. Which of the following is true of medication use agreements?
a. These are voluntary agreements between healthcare clinics or individual prescribers and patients to establish expectations and responsibilities for appropriate opioid prescribing and use.
b. The FDA requires medication agreements under the opioid REMS program.
c. The DEA requires that states without a PMP use medication use agreements.
d. Pharmacists that rely on the terms of the medication use agreements will not be responsible for improper dispensing of controlled substance prescriptions.

17. Medicare Part D plans that seek to implement quantity limits for single-agent opioids that do not contain acetaminophen must first receive approval from the Centers for Medicare and Medicaid Services.
a. True
b. False

18. Which of the following does not represent a healthcare plan intervention that may be used as a tool for pharmacists to properly dispense opioid prescriptions?
a. Prospective and retrospective drug utilization review
b. The FDA REMS for long-acting, extend-release opioids
c. Formulary management
d. Use of clinical pharmacists to communicate with practitioners who prescribe opioids

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19. **Only pharmacies, not the pharmacist, may be sanctioned by DEA for monetary penalties resulting from violations related to controlled substances.**
    a. True
    b. False

20. **Which of the following is generally a common sense approach for the pharmacist to follow when filling prescriptions containing opioids?**
    a. The pharmacist should assume that the prescription is fraudulent unless proven otherwise.
    b. The pharmacist may rely solely on another store pharmacist's word when determining whether a patient's opioid prescriptions are appropriate.
    c. The pharmacist must conduct appropriate due diligence on opioid prescriptions to ensure the validity.
    d. Prescriptions that appear to be properly written with all the federal and state required elements should be considered appropriate by the pharmacist.